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10/552,686

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EXAMINER

COLLINS, CYNTHIA E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,686	Applicant(s) MULET SALORT ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 18 is/are rejected.
- 7) ☒ Claim(s) 16 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>101105, 12706</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election without traverse of **Group XII**, claim(s) 15-16 and 18, drawn to an isolated protein of SEQ ID NO:4 belonging to the family of CHMP proteins, and use of the protein for modifying abiotic stress tolerance in yeast, in the reply filed on December 19, 2007, is acknowledged.

In the reply filed on December 19, 2007:

Claims 1-14, 17 and 20-26 are cancelled.

Claims 15, 18 and 19 are currently amended.

Claims 15-16 and 18-19 are pending.

Applicant also requests inclusion of claim 19 in the examined subject matter.

Claim 19 is withdrawn from consideration as being directed to a nonelected invention because the isolated nucleic acid of claim 19 is not linked to the isolated protein of the elected subject matter by a special technical feature.

Claim 19 is also withdrawn from consideration because Claim 19 is directed to subject matter (an isolated nucleic acid) that differs in classification, structure, function and use from the elected subject matter (an isolated protein), and would thus require a different field of search. the prior art applicable to an isolated protein would additionally not necessarily be applicable to an isolated nucleic acid, and an isolated nucleic acid raises different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Additionally, because claim 15 as currently amended is no longer directed to the elected subject matter (use of a protein), claim 15 is also withdrawn from consideration as being directed to a nonelected invention.

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Claims 16 and 18 are examined on the merits herein.

Drawings

The drawings are objected to because the details in Figures 1, 2 and 5 are not visually discernable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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The disclosure is objected to because of the following informalities: the disclosure does not comply with 37 CFR 1.182, which requires that reference be made to a sequence by use of the sequence identifier, preceded by "SEQ ID NO:." in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Appropriate correction is required.

Claim Objections

Claim 16 is objected to because it is directed in part to nonelected inventions (proteins comprising a SEC14 domain, CRYO5 like plant proteins, and the use of proteins for modifying abiotic stress tolerance in a plant, plant part or plant cell). Appropriate correction is required.

Claim 18 is objected to because it is directed in part to nonelected inventions (SEQ ID NOS:2, 6, 8 and 10). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claim is directed to an isolated protein (a) comprising the sequence as given in SEQ ID NO 4; (b) comprising a sequence having at least 55 %, alternatively 60%, 70%, 80%, preferably 90%, more preferably 95%, 96%, 97%, 98% or 99% sequence identity to the full length sequence as given in SEQ ID NO 4; (c) comprising a substitution variant or insertion variant of (a); (d) according to any of (a) to (c), comprising substitutions with corresponding naturally or non-naturally altered amino acids.

The specification describes SEQ ID NO:4 (also designated CRYO2) as the amino acid sequence predicted to be encoded by a cDNA obtained from *Beta vulgaris*, which cDNA, when expressed in yeast, confers cold stress tolerance thereto (page 8; pages 37-40; Figure 2; sequence listing). The specification also describes SEQ ID NO:4 as having an SNF7 domain, and as belonging structurally to the CHMP protein family (page 8).

The specification does not describe other proteins that are amino acid sequence variants of SEQ ID NO:4 and that function in the same manner as SEQ ID NO:4.

The Federal Circuit has affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or

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some combination of such characteristics.” See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus of protein sequences which encompasses numerous undisclosed and uncharacterized amino acid sequences that (b) have at least 55 %, alternatively 60%, 70%, 80%, preferably 90%, more preferably 95%, 96%, 97%, 98% or 99% sequence identity to the full length sequence as given in SEQ ID NO 4, or that (c) comprise any unspecified substitution variant or insertion variant of SEQ ID NO:4, or that comprise any unspecified substitutions with corresponding naturally or non-naturally altered amino acids of SEQ IOD NO:4 or (b) or (c), nor the structural features unique to the genus that are correlated with conferring cold tolerance.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein comprising the sequence as given in SEQ ID NO 4, does not reasonably provide enablement for other isolated proteins comprising other amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim.

The claim is broadly drawn to an isolated protein (a) comprising the sequence as given in SEQ ID NO 4; (b) comprising a sequence having at least 55 %, alternatively 60%, 70%, 80%, preferably 90%, more preferably 95%, 96%, 97%, 98% or 99% sequence identity to the full length sequence as given in SEQ ID NO 4; (c) comprising any unspecified substitution variant or insertion variant of (a); (d) according to any of (a)

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to (c), comprising any unspecified substitutions with corresponding naturally or non-naturally altered amino acids.

The specification discloses that expression in yeast of a cDNA obtained from *Beta vulgaris*, which cDNA is predicted to encode the amino acid sequence of SEQ ID NO:4, confers cold stress tolerance to the yeast (pages 37-40; Figure 2). While the specification does not disclose any direct evidence of function for an isolated protein comprising the sequence as given in SEQ ID NO 4, a cold stress tolerance function for this protein can reasonably be inferred given the nature of the expression system used.

The specification does not disclose isolated proteins that are variants of SEQ ID NO:4 that function to confer cold tolerance to yeast.

The full scope of the claimed invention is not enabled because the functional attributes of amino acid sequence variants are unpredictable, since a change of one or more amino acids in a polypeptide can alter or eliminate its function.

See, for example, Broun P et al. (Catalytic plasticity of fatty acid modification enzymes underlying chemical diversity of plant lipids. *Science*. 1998 Nov 13;282(5392):1315-7), who teach that as few as four amino acid substitutions can change an oleate 12-desaturase to a hydroxylase (paragraph spanning pages 1316-1317).

See also, for example, Rhoads D.M. et al. (Regulation of the cyanide-resistant alternative oxidase of plant mitochondria. Identification of the cysteine residue involved in alpha-keto acid stimulation and intersubunit disulfide bond formation. *J Biol Chem*. 1998 Nov 13;273(46):30750-6), who teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3),

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whereas mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

In the instant case Applicant has not provided guidance with respect to the particular functional attributes of variants of SEQ ID NO:4. Absent such guidance it would require undue experimentation for one skilled in the art to use variants of SEQ ID NO:4, as one skilled in the art would have to make and then test a variety of different amino acid sequence variants for a variety of different specific activities in order to determine the particular functional attributes, if any, of each variant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 provides for the use of a protein, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition

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of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Bevan M. et al. (Putative uncharacterized protein F19B15.190 (At4g29160), Uniprot Accession No. Q9SZE4, 01-MAY-2000).

The claim is drawn to an isolated protein comprising a sequence having at least 80% sequence identity to the full length sequence as given in SEQ ID NO 4.

Bevan M. et al. teach an isolated protein comprising a sequence having 85% sequence identity to the full length sequence as given in SEQ ID NO 4.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC

